# Optimizing the Preparation Regimen Prior to Colonoscopy Procedure with the Pure-Vu® System

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## INTRODUCTION

Colonoscopy is considered the "gold standard" for detecting and treating abnormalities in the colon. Adequate colon cleansing is imperative for enhancing the efficacy of colonoscopy and avoiding early repeat colonoscopy procedures. The Pure-Vu® System (Motus GI Ltd.) is an FDA 510(k) cleared device which facilitates intraprocedural cleansing of patients with poorly prepared colons. This first United States (US) cohort, prospective study sought to evaluate the performance of the Pure-Vu System in cleansing colons in patients requiring a colonoscopy and utilizing only various minimal preparation regimens.

**The Pure-Vu System** fits over most standard and pediatric colonoscopes, allowing physicians to cleanse the colon in a safe and effective manner to gain clear visualization of the colonic mucosa.


## METHODS

The study was initially designed to compare 2 different minimal bowel preparation regimens. Initially patients were randomized to receive one of 2 minimal bowel preparations: 3 doses of 17gr MiraLAX each mixed in 8.5 oz. of clear liquids or 2 doses of 7.5oz Magnesium Citrate (MgC) each taken with 19.5oz of clear liquid. A study amendment early on replaced the MiraLAX arm, due to obvious inferior Boston Bowel Preparation Scoring (BBPS) from the outset. The replacement arm consisted of 2 doses of 5oz MgC taken with 16oz of clear liquid. All patients were allowed a low residue diet on the day prior and were asked to avoid seeds and nuts for 5 days prior to their procedure. Study objectives evaluated for each study arm included: (1)Improvement of colon cleansing from presentation baseline to completion of the procedure (as assessed by the BBPS) through the use of the Pure-Vu System, (2)Time required to reach the cecum, (3)Total procedure time, and (4)Safety.

**Table 1:** Patient Demographics and Indication for Colonoscopy

| | MgC 10oz | MgC 15oz | MiraLAX 25.5oz |
|---|---|---|---|
| Number of cases | 17 | 21 | 8 |
| Age (mean ± SD) | 59.94 ± 9.04 | 62.90 ± 9.99 | 58.13 ± 9.09 |
| BMI | 29.91±3.48 | 29.08 ± 6.06 | 27.45 ± 6.50 |
| Male (%) | 76% | 52% | 38% |
| **Indication for procedure (%)** | | | |
| CRC Screening | 58.8% | 43% | 62.5% |
| Polyp Surveillance | 17.6% | 33% | 37.5% |
| Family history (1st. Degree relative) | 5.9% | 10% | - |
| Bleeding / Anemia | 17.6% | 14% | - |

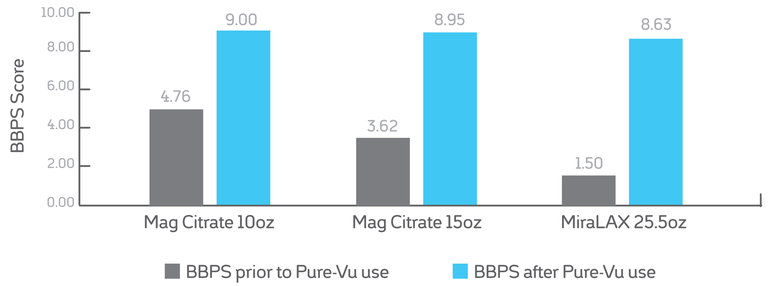
**Table 2:** Time to Cecum and Total Procedure Time

| | MgC 10oz | MgC 15oz | MiraLAX 25.5oz |
|---|---|---|---|
| Time to cecum (Minutes) | 11.94±10.15 | 11.86±8.42 | 16.75±7.46 |
| Total procedure time (Minutes) | 23.99±11.44 | 25.88±11.20 | 34.11±10.37 |

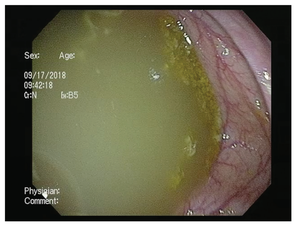
## RESULTS

Forty-nine subjects were enrolled in the study. One subject was withdrawn prior to the procedure due to non-compliance with the diet and preparation instructions including eating solid food just prior to the scheduled procedure. Two patients had a colonic stricture that resulted in an incomplete procedure, and thus were excluded from the analysis. Forty-six subjects (59% males), mean age of 61±9.48 years with a mean BMI of 29±5.28 were included in the analysis. No significant differences were found between the 3 groups with regard to demographics or indication for colonoscopy (Table 1 & 2). No serious adverse events related to the device were reported. The mean BBPS at baseline and post cleansing procedure were 3.67±2.86 and 8.91±0.35, respectively. Each of the 3 study arms revealed significant differences between the baseline preparation and that seen post cleansing (Figure 1). Comparing the mean BBPS rating for both pre- and post- Pure- Vu use, the MiraLAX arm was inferior (p. value <0.05) to both Mag Citrate arms. The mean time to reach the cecum and the mean total procedure time were 12.74±8.96 minutes and 26.61±11.48 minutes, respectively. Analysis showed no significant difference in the total procedure time between the three study arms (Table 2).

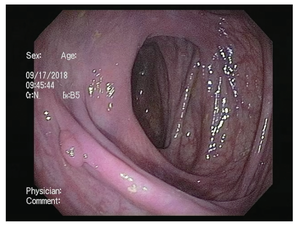
**Figure 1.** BBPS Rating Before and After the Use of the Pure-Vu System




Prior to Use



After Use



## DISCUSSION

In the first United States prospective cohort study we evaluated the effectiveness of the Pure-Vu System in patients who were given minimal pre-procedural prep and were allowed three (3) low residue meals on the day prior to the procedure. Three (3) different pre-procedural prep regimens were offered as part of the study, Mag Citrate 10oz, Mag Citrate 15oz and MiraLAX 25.5oz; consumption of all resulted in inadequately prepped colons. The use of the Pure-Vu System enabled outstanding intraprocedural cleansing of the colon and ensured successful completion of all colonoscopies performed (100% success rate). Although there were only 46 patients in the study, the results were significant. The use of the Pure-Vu System added some time to the procedure, but the total procedure time was still around 25 minutes in this single operator's study.

## CONCLUSION

The Pure-Vu System was found to be safe and effective in colonic cleansing in patients who underwent minimal bowel preparation regardless of the type of minimal bowel preparation prescribed.